

5. 510(K) SUMMARY

Date Prepared:

MAR - 3 2008

November 2, 2007

Owner and Contact Person:

Name: Sharyn Orton, PhD

Title: Director, Regulatory Affairs
Fenwal, Inc.

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Owner/Operator Number 9098803

Device Name(s):

(4C2160) Blood Component Recipient Set with Standard Size Filter

(4C2161) Y-Type Blood Component Recipient Set with Standard Size Filter

(4C2223) Blood Component Infusion Set with Side Arm Luer Connector

Common Name:

Set, Blood Transfusion

Classification Name:

Intravascular Administration Set (21 CFR 880.5440)

Legally Marketed Device:

Blood/Solution Set with Pressure Pump (K881321)

Radiation Sterilized Administration Sets (K811078)

Device Description

Fenwal markets a broad range of intravascular administration sets for administration of I.V. solutions or blood involving hundreds of different sets marketed. While the design of these sets differs for each particular application, they are all based on a common basic design involving polyvinyl chloride extruded tubings, with attendant extruded or injection molded connecting parts of other thermoplastics (such as acrylic, ABS, nylon, and similar polymers) plus latex and synthetic rubber injection sites.

Transfusion sets have been classified by the General Hospital and Personal Use Section of the General Medical Device Panel as Class II in 21 CFR 880.5440 under the classification name intravascular administration set.

Statement of Intended Use

Administration of blood and blood by-products.

Technological Characteristics

Fenwal Blood Transfusion Sets are designed to transfuse blood components such as platelets, plasma products, cryoprecipitate and leukocytes. The Y-type set has a small surface area filter and the set offers the user the flexibility of starting the infusion with saline and rinsing the container and tubing of blood components before completing the transfusion. The transfusion set with the luer connector has a filter screen in the distal needle/catheter adapter to minimize platelet loss. The side arm Luer connector facilitates syringe-push technique, suitable for infusion.

Conclusion

The devices listed in this summary have been cleared for Baxter Healthcare Corporation under 510(k) numbers K881321 and K811078, which showed the product to be safe and effective. Since this 510(k) notification is only being submitted to obtain a number under Fenwal, the safety and effectiveness for these products have not changed.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2008

Sharyn Orton Ph. D.
Director, Regulatory Affairs
Fenwal, Incorporated
Three Corporate Drive, 2nd Floor
Lake Zurich, Illinois 60047

Re: K073339

Trade/Device Name: (4C2160) Blood Component Recipient Set with Standard Size Filter
(4C2161) Y-Type Blood Component Recipient Set with Standard Size Filter
(4C2223) Blood Component Infusion Set with Side Arm Luer
Regulation Number: 21 CFR 880.5440
Regulation Name: Blood Transfusion Set
Regulatory Class: II
Product Code: BRZ
Dated: February 7, 2008
Received: February 11, 2008

Dear Dr. Orton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

4. INDICATION FOR USE STATEMENT

510(k) Number (If Known):

Not yet assigned

Device Names:

(4C2160) Blood Component Recipient Set with Standard Size Filter

(4C2161) Y-Type Blood Component Recipient Set with Standard Size Filter

(4C2223) Blood Component Infusion Set with Side Arm Luer

Indication(s) for Use:

Administration of blood and blood by-products.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073339